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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,874	12/20/2001	Chika Nakanishi	217408US0CONT	4217

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EXAMINER

MORRIS, PATRICIA L

ART UNIT PAPER NUMBER

1625

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/022,874

Applicant(s)

NAKANISHI ET AL.

Examiner

Patricia L. Morris

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2004 and 16 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

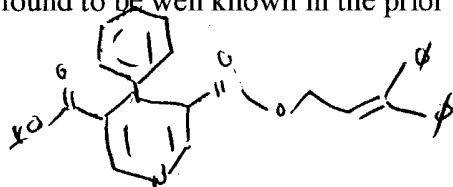
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DETAILED ACTION

Claims 1-30 are under consideration in this application.

Election/Restrictions

Again, in addition to the elected piperidine compound set forth on page 3 of the previous Office action, the search has been extended to include an additional species which is found to be well known in the prior art.



The elected compounds are the **elected invention**.

The restriction requirement is deemed sound and proper and is hereby maintained and made FINAL..

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 16-19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Again, Claims 16-19 violate 35 U.S.C. 101 and 35 U.S.C. 112, since it is drafted in terms of use. See *Clinical Products vs. Brenner*, 255 F. Supp. 151; 149 USPQ 475 (D.C. District of Columbia 1966).

Contra to applicants' arguments, claims 16-19 are drawn to nonstatutory subject matter and are not even proper claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Uneyama et al. and Niwa et al. for the reasons set forth in the record.

Uneyama et al. and Niwa et al. generically embrace the instant compound having the same use. Note, for example, the compounds of formula (I) in columns 2-4, or the compound recited in column 65 of Uneyama et al.

Applicants appear to argue that one having ordinary skill in the art would not have been motivated to produce the compounds encompassed by the claims. The

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motivation is not abstract but is always related to the properties or uses that one having ordinary skill in the art would have expected the resulting compound to exhibit. In situations involving chemical compounds bearing a close structural similarity, the requisite motivation stems from the expectation that compounds exhibiting closely similar structures will exhibit similar properties. In the situation here, one would not have to modify the disclosure of Uneyama et al. and Niwa et al., but merely employ compounds that are generically embraced by the disclosed formulas of the references. As previously discussed, the requisite motivation for producing the claimed compounds stems from the fact that they are generically disclosed. Therefore, one having ordinary skill in the art would have found it prima facie obvious to select any on the compounds embraced by the generic formula, including those of the claims, with the expectation that each of them can be used as for the treatment of all diseases.

The data presented in applicants' remarks are of little if any probative value since it is not even in declaration form. The data fails to show any side-by-side comparisons with the prior art compounds.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-19 and 21-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”. These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Again, there is no enablement is shown for the treatment of any of the claimed diseases. The *in vitro* tests are insufficient to show the treatment of any and all unknown cerebrovascular disorders and neurodegenerative diseases, withdrawal symptoms after addiction to drug, AIDS, Parkinson’s disease etc. There are no working examples anywhere in the specification.

Again, the disclosure provides no indication of whether the compounds treat any disease of any claimed disease. Contra to applicants’ arguments in the instant response, the silent as whether to any of the compounds treat any disease.

The state of the prior art is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities (i.e., what compounds can treat which specific disease). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles

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establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic or preventive regimen on its face.

The instant claimed invention is highly unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to therapeutic and preventive effects of any and all diseases including all unknown diseases whether or not the disease is effected by antagonizing an N-type calcium channel would make a difference.

It is the state of the art that there is no known cure or prevention for Alzheimer's disease and that there are only four medications available in the United States available to temporarily slow the early stages of Alzheimer's disease. The current drugs for the treatment of Alzheimer's disease, Aricept, Exelon, Reminyl and Cognex, treat early stages of Alzheimer's disease by delaying the breakdown of acetylcholine. Memantine, which blocks excess amounts of glutamate treats late stage Alzheimer's disease.

(URL: <http://www.cnn.com/2003/Health/conditions/09/24/alzheimers.drug.ap/index.html>)

Contra to applicants' arguments in the instant response, the guidance present in the specification is that of the compounds that are tested that some work, some don't work and some work to a weak extent. Note table 9 of the specification. The claims are drawn to the treatment of any and all diseases with the billions of compounds claimed in claim 1. Applicants even claim any and all unknown heterocyclic compounds.

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The quantity of experimentation needed is undue. One skilled in the art would need to determine what disease out of all known diseases would be benefited by inhibiting a calcium channel and then would further need to which of the claimed compounds would provide treatment of a disease.

Thus, the specification fails to provide sufficient support of the broad use of the compounds of claim 1 for the treatment of any disease. As a result necessitating one of ordinary skill to perform an exhaustive search for which diseases can be treated by which compound of claim 1 in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001, states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.”

Thus, applicants' situation is much like that of In re Kirk, 153 USPQ 48: “What the applicants are really saying to those skilled in the art is take these compounds experiment, and find out what use they have”. Undue experimentation would be required.

In view of the extreme difficulties that have been are still being encountered in the treatment of AIDs, AIDS related dementia, Alzheimer's disease, Parkinson's disease, etc., such utililites are unbelievable on their face, and therefore, they must be supported by sufficient evidence demonstrating such utilities. When the best efforts have failed to achieve a goal, it is reasonable for the PTO to require evidence that such a goal has been accomplished, In re Ferens, 163 USPQ 609.

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In cases directed to chemical compounds, which are being used for their physiological/biological activity, the scope of the claims must have a reasonable correlation to the scope of enablement provided by the specification. See In re Surrey, 151 USPQ 724 regarding sufficiency of disclosure for a Markush group and In re Wiggins, 179 USPQ 421.

Claims 1, 5, 6, 10, 12, 14 and 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The expressions heteroaryl and heteroaryl lower alkyl are employed with considerable abandon throughout claims 1, 5, 6, 10, 12, 14 and 26 with no indication given as to what the heteroaryl groups really are. One, one reading the indication of heterocyclic ring applied by applicants in R⁶ and R⁷, has no idea what size ring is being claimed, or where the hetero atoms are in this unknown ring or what the substituents may be. Moreover, the term substituted is employed in claims 1, 5, 6, 10, 12, 14 and 26 with no indication of the variables. The term contains is open-ended. What are the substituents on the unknown heteroaryl groups?

Contra to applicants' arguments in the instant response, one cannot tell from a simple reading of the claim what is being claimed. One must first conceive of the heteroaryl. Further, applicants are claiming that the instant compounds can treat a staggering list of any and all diseases. Then one must, by preparing the compound himself, determine if the heteroaryl group works or not. Where is the specific claiming and distinctly pointing out? How can applicants regard as their invention inexact

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concepts? The breadth of which they could not have possibly checked out with representative exemplification. The terms are not finite.

Applicants are claiming a compound of the formula. Pure chemistry, a compound. Not a resin of general property ranges, but a pure compound. That compound used for any purpose is taken from the public in a 20-year monopoly to applicants. Then, the public is entitled to know what compound they cannot use. Yet, the claim is not specific to that compound. The public cannot tell what they may not use. How is a claim of the instant breadth defensible in an infringement action?

As applied to pure compounds, *In re Cavallito and Gray*, 134 USPQ 370, and *In re Sus and Schaefer*, 134 USPQ 301, are considered to set the proper applicable standard of required definiteness and support.

The written description is considered inadequate here in the specification. Conception of the intended rings and substituents should not be the role of the reader. Applicants should, in return for a 20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 USC 112, first paragraph. If you (the public) find that it works, I claim it, is not a proper basis of patentability. *In re Kirk*, 153 USPQ 48, at page 53.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1 and 16-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Again, Claims 16-19 are substantial duplicates of claim 1. Claims 16-19 do not further limit claim 1. All the claims are drawn to the compound of claim 1. Applicants are apparently attempting to disguise compound claims as improper use claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-60 of U.S. Patent No. 6,350,766. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant compounds are disclosed therein for the reasons clearly set forth in the previous Office action.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

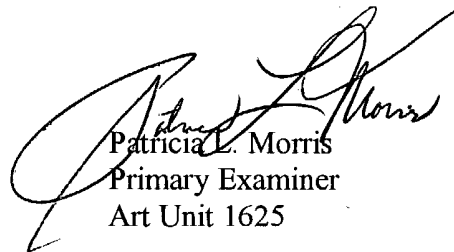
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688. The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Patricia L. Morris
Primary Examiner
Art Unit 1625

plm
November 16, 2004